GLOBAL HEALTH

The NIAID research mission in infectious and allergic diseases is of global importance. When combined, these conditions are the most common causes of preventable human illness and death around the world. Recent concern about emerging and re-emerging infectious diseases and the anthrax biological weapon attacks of October 2001 further reinforced the importance of and added new dimensions to NIAID-supported research in improving early diagnosis, prevention, and control of these pathogens.

Formal recognition of the importance of international research dates back to the International Health Research Act (1960), which gave the Secretary of Health, Education, and Welfare—now the Secretary of Health and Human Services—the authority to conduct research activities outside the United States, provided that the activities were beneficial to the health of U.S. citizens. This authority has been delegated to the NIH and to NIAID. The Public Health Service Act of 1988 (Public Law 100–607) created new HIV/AIDS authorities for the NIH. Subsequently, the NIH Revitalization Act (1993) gave NIAID specific authority to conduct research on tropical diseases that disproportionately affect populations in resource-poor and economically restructuring countries.

In May 2001, NIAID announced its Global Health Research Plan for HIV/AIDS, Malaria, and Tuberculosis. The Global Plan provides short-, medium-, and long-term objectives for treating, preventing, and controlling these diseases by building on the Institute's strong foundation in infectious disease research.

Intramural Research Training and Collaborative Research

NIAID laboratories located in the Bethesda/Washington metropolitan area and Hamilton, Montana, are a significant source of research training for postdoctoral non-U.S. scientists.

Public reaction in India to international effort to reduce cholera outbreaks.

NIAID is also responsible for the management of the Dale and Betty Bumpers Vaccine Research Center (VRC). The host NIAID laboratory usually provides the stipend for the visiting scientists. The research training experience often results in long-term intramural international collaborations once the scientists return to their home countries. In fiscal year (FY) 2004, the largest numbers of NIAID international scientists were from China, India, Japan, France, Canada, Germany, and Italy.

Several years ago, the NIAID Division of Intramural Research (DIR) initiated the International Centers for Excellence in Research (ICER) program to develop sustained research activities in areas of high infectious disease burden through partnerships with scientists in developing countries. The ICER program builds on the long-standing collaboration in malaria research with scientists in Mali, West Africa. While DIR provides the core research program at each ICER site, it is anticipated that other NIAID programs and NIH Institutes and Centers will provide opportunities to expand the research capabilities and programs through the extramural community. Although focused on clinical research in infectious disease, each ICER has the capability to address a range of research and training activities. Current ICER sites are in India, Mali, and Uganda.

The VRC, in collaboration with the Makere University–Walter Reed Project and the NIAID Division of AIDS, will expand ongoing phase I clinical trials in the United States of a novel HIV-1 DNA vaccine directed at the three most globally important HIV-1 subtypes (clades) to Uganda in the coming year.

Domestic Research Awards with an International Component

NIAID funds the vast majority of its international research indirectly through competitive domestic extramural research awards that have an international component. Special emphasis programs have been developed in tropical medicine, emerging infectious diseases, HIV/AIDS, and tuberculosis to take advantage of research opportunities overseas in countries with a disproportionate burden of these diseases.

The infectious disease clinical research efforts supported by NIAID include international sites. Initiated in 1994, the NIAID Tuberculosis Research Unit is supported by a research contract with Case Western Reserve University and funds an international cross-disciplinary team of investigators in Brazil, the Philippines, South Africa, Uganda, and the United States to conduct high-priority research. This research addresses complex clinical questions about tuberculosis and provides the scientific framework upon which high-quality clinical trials of new vaccines, therapeutics, and diagnostics can be conducted. The STD Clinical Trials Units also support sites in Madagascar and Uganda. In addition, the NIAID Bacteriology and Mycology Study Group has begun clinical trials in Thailand. Clinical site development continues in Ghana and Mali for malaria vaccine trials.

NIAID also supports a number of research programs that focus on tropical infectious diseases. The International Collaboration in Infectious Disease Research (ICIDR) Program, initiated in 1980, makes awards to U.S. institutions to engage in substantial international collaboration with overseas institutions in tropical medicine and emerging infectious diseases. The ICIDR Program will be re-competed in FY 2005.

In the context of conducting international research, NIAID supports the development of independent research capacity at NIAID-funded institutions. Numerous training activities have been conducted in Africa, India, South America, and Southeast Asia. This training includes good clinical practices, international research ethics, institutional review board administration, scientific writing, and the design and conduct of clinical trials.

DAIDS research networks have both domestic and international components. The HIV Vaccine Trials Network (HVTN) is a comprehensive, clinically based global network with a mission to develop and evaluate preventive HIV vaccines. The HVTN includes international sites located in Africa (Botswana, Malawi, and South Africa), Asia (China, India, and Thailand), the Caribbean (Dominican Republic, Haiti, Jamaica, Puerto Rico, and Trinidad and Tobago), and South America (Brazil and Peru).

The HIV Prevention Trials Network (HPTN) is a second worldwide collaborative effort established by NIAID to evaluate the safety and efficacy of nonvaccine prevention interventions. The HPTN consists of domestic and international units. International sites are located in Brazil, China, India, Malawi, Peru, Russia, South Africa, Tanzania, Thailand, Uganda, Zambia, and Zimbabwe.

NIAID's Acute HIV Infection and Early Disease Research Program is collaborating with the University of Alabama at Birmingham and the University Teaching Hospital in Lusaka, Zambia, to study the effects of a short course of antiretroviral therapy on the viral load in newly infected persons when it is initiated early after acute HIV infection.

The NIAID Centers for AIDS Research (CFARs) support a multidisciplinary environment that promotes basic, clinical, behavioral, and translational research in the prevention, detection, and treatment of HIV infection and AIDS. Current CFAR collaborations are taking place in Belize, Kenya, Mexico, Peru, Thailand, Uganda, and Zambia.

International Awards

NIAID and the NIH accept investigator-initiated research proposals from international scientists and permit international scientists to respond to most program announcements and requests for applications. To be funded, international applications must receive a competitive peer review score and be approved by the National Advisory Allergy and Infectious Diseases Council on the basis of their uniqueness and/or program relevance. International scientists also may be eligible to compete for NIAID research contracts when U.S. institutions cannot carry out the project (e.g., pertussis vaccine trials in Italy and Sweden) or when the domestic applications are not responsive to the solicitation.

Historically, international awards have accounted for about 1 percent of the NIAID budget. As basic research results in new or improved products that require evaluation in populations with heavy burdens of disease, this amount is expected to increase. Furthermore, long-term NIAID investment in collaborative research has resulted in the development of overseas sites capable of independent research. The establishment of the Tropical Medicine Research Centers (TMRC) program a decade ago was a reflection of this phenomenon. Currently, TMRCs are located in Brazil, Chile, Colombia, and Peru.

In FY 2001, NIAID launched the Comprehensive International Program of Research on AIDS (CIPRA). CIPRA provides long-term support directly to developing countries to plan and implement a comprehensive HIV/AIDS prevention and research agenda relevant to their populations and to strengthen the infrastructure required to carry out this research. In FY 2004, CIPRA awarded five new CIPRA grants to the following countries: Cambodia, Haiti, Peru, Russia, and Thailand. In addition, there are ongoing CIPRA projects in Argentina, Brazil, China, Egypt, the Republic of Georgia, Kenya, Mozambique, Senegal, and South Africa.

In FY 2003, NIAID initiated the International Research in Infectious Diseases (IRID) Program, which consists of small grants programs specifically designed to help foreign scientists in resource-constrained countries obtain NIH funding. To date, IRID awards have been made to investigators in Africa, Eastern Europe, South America, and the South Pacific.

Official Bilateral Programs

In addition to regular scientific channels, the United States often develops formal, bilateral scientific agreements with foreign governments or organizations at the level of the President, the Department of Health and Human Services (DHHS), the NIH, or NIAID. NIAID carries out these programs with budgeted funds unless special or supplementary funds are made available. NIAID has actively participated in bilateral programs involving Brazil, China, France, the Republic of Georgia, Germany, India, Italy, Japan, Russia, South Africa, and Taiwan. Of particular interest is the U.S.–Japan Cooperative Medical Science Program (USJCMSP), which consists of committees of senior scientists and panels of experts in high-priority diseases of the Pacific Basin. Both the Joint USJCMSP Committee and Joint Panels meet annually, alternating countries in conjunction with scientific conferences. The USJCMSP has organized annual workshops on emerging and re-emerging infectious diseases in the Pacific Basin at different sites in the region. Active priority areas are AIDS, acute respiratory infections, cholera and other bacterial enteric diseases, environmental genomics and carcinogenesis, infectious hepatitis, immunology,

leprosy/tuberculosis, nutrition and metabolism, parasitic diseases, and viral diseases.

International Agencies and Organizations

NIAID has joined with other organizations to enhance scientific collaborations in combating infectious diseases. Examples include the Presidential Millennium Vaccine Initiative; the Global Alliance for Vaccines and Immunization; the Multilateral Initiative on Malaria in Africa; the International Cooperative Biodiversity Groups Program; and the DHHS–State Department Biotechnology Engagement Program and the Civilian Research and Development Foundation, both of which provide support to scientists in newly independent states of the former Soviet Union to conduct collaborative research on problems of public health importance.

NIAID staff members also participate on the scientific boards of and as consultants to the World Health Organization, the Pan American Health Organization, and the U.S. Agency for International Development.

On February 23, 2004, the first $350 million in funding of the President's Emergency Program for AIDS Relief (PEPFAR) was made available and began reaching people in need only 2 weeks later. The second distribution of funding—$500 million—will continue to build on prevention, treatment, and care efforts. In total, PEPFAR will spend $2.4 billion on global AIDS through FY 2005. PEPFAR countries include Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia. NIAID currently supports the work of PEPFAR in Ethiopia, Haiti, and South Africa.